510(k) Summary: UniVise™ Spinous Process Fixation Plate	
Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Kristen Meany, MS, CQA, RAC Project Manager, Regulatory Affairs Phone: 201-760-8070 Fax: 201-962-4070 Email: kristen.meany@stryker.com
Date Prepared	September 20 2013
Trade Name	UniVise™ Spinous Process Fixation Plate
Common Name	Spinous Process Fixation Plate
Proposed Class	Class II
Classification Name and Number	Spinal interlaminal fixation orthosis, 21 C.F.R. 888.3050
Product Code	PEK
Predicate Devices	The UniVise™ Spinous Process Fixation Plate was shown to be substantially equivalent to the devices listed below: • Affix® Spinous Process Plate System, NuVasive Incorporated, K131238 • VertiFlex® Spinous Fixation Plate, VertiFlex Incorporated, K122509
Device Description	The UniVise™ Spinous Process Fixation Plate is a one-piece bilateral locking plate device which attaches to the posterior non-cervical spine by securely grasping two adjacent spinous processes. The S.P.F.P is available in multiple sizes to accommodate different anatomical requirements, and it is composed entirely of titanium 6Al-4V alloy. The UniVise™ Spinous Process Fixation Plate may be implanted by either conventional surgical methods, or via minimally-invasive techniques. Proprietary manual instrumentation for implantation of the S.P.F.P is available for both conventional and minimally-invasive surgical procedures. When the UniVise™ Spinous Process Fixation Plate is used as supplemental fixation in interbody fusion procedures, its use is limited to the treatment of degenerative disc disease (DDD) of the lumbosacral spine (L2-S1).
Intended Use	The UniVise™ Spinous Process Fixation Plate is a posterior, non-pedicle supplemental fixation device intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purposes of achieving supplemental fusion in the following conditions: Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); and/or tumor. The UniVise™ Spinous Process Fixation Plate is intended for use with bone graft, and is not intended for stand-alone use.

Summary of the Technological Characteristics	As was established in this submission, the UniVise™ Spinous Process Fixation Plate is substantially equivalent and has equivalent technological characteristics to other predicate devices cleared by the FDA as demonstrated through comparison in areas such as design, labeling, intended use, material composition, and function.
Summary of the Performance Data	The purpose of this 510(k) is to modify the Surgical Technique for the subject UniVise™ Spinous Process Fixation Plate. No device design changes have been made to the predicate VertiFlex® Spinous Process Fixation Plate (commercially distributed as the UniVise™ Spinous Process Fixation Plate by Stryker Spine) previously cleared in K122509. No new performance data was generated for the purpose of this submission.
Conclusions	The UniVise™ Spinous Process Fixation Plate is as safe and effective as the predicate devices as it has the same intended uses and similar indications for use, technological characteristics, and principles of operation as its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 18, 2013

Stryker Spine
Kristen Meany, MS, CQA, RAC
Project Manager, Regulatory Affairs
2 Pearl Court
Allendale, New Jersey 07401

Re: K132968
Trade/Device Name: UniVise™ Spinous Process Fixation Plate
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: September 26, 2013
Received: September 27, 2013

Dear Ms. Meany:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K132968

Device Name: Stryker Spine UniVise™ Spinous Process Fixation Plate

Indications for Use:

The UniVise™ Spinous Process Fixation Plate is a posterior, non-pedicle supplemental fixation device intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); and/or tumor. The UniVise™ Spinous Process Fixation Plate is intended for use with bone graft, and is not intended for stand-alone use.

Prescription Use ___X__ (Part 21 C.F.R. 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 C.F.R. 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132968

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